K083594

JUL 21 2009

510K Summary (K083594)

Submitted by:

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July 17, 2009

Device:

Trade Name:	Foam Seal Catheter
Proposed Classification Name:	Cannula, Manipulator/Injector, Uterine
Common/Usual Name:	HSG Catheter
Regulation Number:	Unclassified
Product Code:	LKF
Class:	Unclassified

Device Description:

Foam Seal Catheter is a single channel catheter intended for use during hysterosalpingogram and saline Infusion sonogram. Foam Seal Catheter is a simplified version of double-channel balloon HSG catheter. This device has a single channel catheter of 1.6mm to 3mm in diameter and has a length of 370mm. Both ends of this catheter are open. The outer end has a luerlock device. A two way lock is attached to this end. The inner end is used to introduce fluid into the cavity of uterus. An introducer or an external cannula of 170mm is placed on its mid-segment. Both catheter and cannula are made of plastic material. A cone-shaped foam component is attached close to inner end so it can be placed in the cervical canal during the procedure. The foam replaces a balloon to maintain fluid seal and to keep the catheter in place.

Fluid media is injected into the cavity of uterus using this catheter with a syringe. Endometrial cavity is distended with the injected fluid. Radiology procedures or ultrasound examination is performed at this time and images of the cavity of the uterus is taken. There are several advantages to this device. This is a single channel device and is usually cheaper. Foam segment seals the cervical canal and keeps the catheter in place without the need of an assistant.

Predicate Device:

This Foam Seal catheter is comparable to existing predicate devices: H/S Elliptosphere Catheter set with 510K number K 013972.

Intended Use:

The Foam Seal SIS/HSG Catheter is intended for introduction of liquid into the uterine cavity for ultrasonogram and radiology procedure of the uterus and fallopian tubes.

Summary of Technologies:

The Foam Seal Catheter has the same technological characteristics as the predicate device, H/S Elliptosphere Catheter. The intended use and operating principles are identical. The Foam Seal catheter is individually packaged in ETO sterilized blister pack for single use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Al Muzzammel, M.D.
President
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JUL 21 2009

Re: K083594
Trade/Device Name: Foam-Seal Catheter
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: June 22, 2009
Received: June 24, 2009

Dear Dr. Muzzammel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLAGICAL HEALTH

Indications for use

10(K) Number (if known): 510K# K083594

Device Name: Foam-Seal Catheter

Indications for Use:

Injection of fluid into the uterine cavity during Saline Infusion sonogram (SIS) & hysterosalpinogram (HSG). Following are some Clinical Indications:

1. Infertility.
2. Menorrahagia.
3. Dysmenorrhea.
4. Suspected Endometrial Polyp.
5. Uterine Fibroid.
6. Amenorrhea due to Uterine Synechea (Asherman Syndrome).
7. Congenital Uterine Anomaly.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083594

Exhibit #3